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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,412	08/14/2001	Akiyoshi Kawaoka	212628US0DIV	8372

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EXAMINER

KALLIS, RUSSELL

ART UNIT PAPER NUMBER

1638

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/928,412

Applicant(s)

KAWAOKA ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 11/19/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3, 11-18 and 20 is/are pending in the application.
- 4a) Of the above claim(s) 13, 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3, 11, 12, 14-16 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/282,164.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: attached sequence report

DETAILED ACTION

Rejection of claims 3-4, 11-12 and 14-16 under 35 U.S.C. 102(b) is withdrawn in view of Applicant's amendments and arguments.

Claims 1-2, 4-10 and 19 have been canceled. Claims 3, 11-18 and 20 are pending. Claims 13, 17 and 18 are withdrawn. Claims 3, 11-12, 14-16 and 20 are examined.

Sequence Rules

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth: Claim 3 recites a common DNA sequence instead of a sequence identifier.

§ 1.821 Nucleotide and/or amino acid sequence disclosures in patent applications;

(d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

Applicant must amend the claims, specification, and/or drawings to insert sequence identifiers.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 11-12 and 14-16 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 5/19/2004. Applicant's arguments filed 11/19/2004 have been considered but are not deemed persuasive.

Applicant asserts that the claim limitations of Claim 3 meet the Patent Office's Guidelines for written description according to those requirements set forth in Example 9 of the Written Description Guidelines (response page 4). Applicant has not set forth highly stringent hybridization conditions. The written description guidelines of Example 9 recite 6XSSC at 65C as an example of highly stringent conditions, while Claim 3 recites 6XSSC at 55C; and thus Applicant has not met the written description requirement for describing a genus.

Claims 3, 11-12 and 14-16 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA of SEQ ID NO: 1 encoding a transcription factor controlling a phenylpropanoid pathway in Tobacco and Tobacco plant cells and Tobacco plants transformed with a vector comprising an antisense DNA of SEQ ID NO: 1, does not reasonably provide enablement for an isolated DNA that hybridizes to SEQ ID NO: 1 and encodes a transcription factor controlling a phenylpropanoid biosynthesis pathway and plant cells and plants transformed with an antisense construct thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This

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rejection is maintained for the reasons of record set forth in the Official action mailed 5/19/2004.

Applicant's arguments filed 11/19/2004 have been considered but are not deemed persuasive.

Applicant asserts that in view of the written description of the invention the claimed invention is enabled because one would simply have to isolate the encoding DNA, and test for the encoded protein's ability to bind the common sequence and then transform a plant to determine whether it would control a phenylpropanoid biosynthetic pathway, wherein the specification defines the phenylpropanoid biosynthesis pathway as a complicatedly branched reaction system in plants relating to the biosynthesis of cell wall components, flower pigments, and antibacterial substances (page 3, lines 10-15 of the specification). Based upon Applicant's limited guidance one cannot predict which embodiments would be operable and thus undue trial and error experimentation would be required by one of skill in the art to isolate and test the multitude of non-exemplified DNA sequences that hybridize to SEQ ID NO: 1 and to transform and screen a myriad of non-exemplified transformed plants from any species for the ability of any isolated DNA that hybridized to SEQ ID NO: 1 to encode a transcription factor that would control a phenylpropanoid biosynthetic pathway when transformed into a plant cell or plant encompassed by the claims. See *In re Fisher*, 166 USPQ 18, 24(CCPA 1970) which teaches "That paragraph (35 USC 112, first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical

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reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Baltz R. *et al.* The Plant Journal, 1992, Vol. 2; pages 713-721 in light of Baltz R. *et al.* Sex. Plant Reproduction, 1996; Vol. 9, pp. 264-268 and the attached sequence report.

Applicant broadly claims any nucleotide sequence that hybridizes to SEQ ID NO: 1 to a nucleotide sequence that hybridizes to SEQ ID NO: 1 under low stringency conditions at 55° C using 6X SSC salt buffer with no wash conditions, that binds to a common sequence wherein the nature of the binding is unspecified, and which controls a phenylpropanoid biosynthesis pathway, wherein the specification defines the phenylpropanoid biosynthesis pathway as a complicatedly branched reaction system in plants relating to the biosynthesis of cell wall components, flower pigments, and antibacterial substances (page 3, lines 10-15 of the specification).

Baltz (1992) teaches an isolated polynucleotide encoding a pollen specific transcription factor SF3 (HA-PLIM-1) from sunflower comprising zinc finger binding domains, basic domains, and a pentapeptide repeat at the C-terminus (page 715, page 716 column 2, and page 717 column 1, beginning of Discussion); and Baltz (1996) teaches binding of SF3 (HA-PLIM-1)

to DNA (see Figure 1 and page 267); wherein the polynucleotide sequence encoding the SF3 of sunflower would hybridize to SEQ ID NO: 1 under the stringency conditions recited and would bind the common sequence recited in Claim 3 under unspecified binding conditions; and thus the reference teaches all the limitations of Claim 3.

Double Patenting

Claims 3, 11-12 and 14-16 remain and new Claim 20 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 6-8 of U.S. Patent No. 6,303,847. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '847 Patent is drawn to SEQ ID NO: 1 isolated from Tobacco that encodes a transcription factor controlling a phenylpropanoid pathway and transformed plant cells and plants. This rejection is maintained for the reasons of record set forth in the Official action mailed 5/19/2004. Applicant's arguments filed 11/19/2004 have been considered but are not deemed persuasive.

Applicant asserts that may they consider filing a Terminal Disclaimer when the Patent Office finds the pending claims allowable (response page 6). Applicant's remarks are noted.

All claims are rejected.

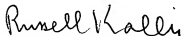
Claims 11-12, 14-16 and 20 are deemed free of the prior art given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO: 1.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Russell Kallis Ph.D.
February 17, 2005

